



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 721**

**[EPA-HQ-OPPT-2015-0810; FRL-9951-77]**

**RIN 2070-AB27**

### **Significant New Use Rule on Certain Chemical Substances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for three chemical substances which were the subject of premanufacture notices (PMNs). The applicable review periods for the PMNs submitted for these chemical substances all ended prior to June 22, 2016, the date on which President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act which amends TSCA). This action would require persons who intend to manufacture (defined by statute to include import) or process any of the chemical substances for an activity that is designated as a significant new use by this proposed rule to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the intended use within the applicable review period.

Manufacture and processing for the significant new use is unable to commence until EPA has conducted a review of the notice, made an appropriate determination on the notice, and take such actions as are required with that determination.

**DATES:** Comments must be received on or before [*insert date 30 days after date of publication in the* **Federal Register**].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2015-0810, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and

Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: *moss.kenneth@epa.gov*.

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this proposed rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

Manufacturers (including importers) or processors of one or more subject chemical substances (NAICS codes 325 and 324110), *e.g.*, chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that

the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance to a proposed or final rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

*B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

## **II. Background**

*A. What Action is the Agency Taking?*

EPA is proposing these SNURs under TSCA section 5(a)(2) for three chemical substances which were the subject of PMNs P-15-276, P-15-378, and P-15-559. These SNURs would require persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity. In accordance with the procedures at § 721.160(c)(3)(i), in the **Federal Register** publication of May 16, 2016 (81 FR 30452) (FRL- 9944–77) EPA issued direct final SNURs on these chemical substances, which are the subject of PMNs. EPA received notices of intent to submit adverse comments on these SNURs. Therefore, as required by § 721.160(c)(3)(ii), EPA withdrew the direct final SNURs in the **Federal Register** of July 14, 2016 (81 FR 45416) (FRL- 9948-81), and is now issuing this proposed rule on these three chemical substances. The records for the direct final SNURs on these chemical substances were established as docket EPA-HQ-OPPT-2015-0810. Those records include information considered by the Agency in developing the direct final rule. While notices of intent to submit adverse comments were received during the direct final rule phase, no substantive comments were submitted. EPA awaits the adverse comments during the open comment period for this proposed rule. Comments received on the two isocyanate PMN chemicals in today's proposed rule will be addressed in a final rule with isocyanate PMN chemicals that were the subject of previous proposed rules published in the Federal Register at 80 FR 845 (January 7, 2015) and 81 FR 21830 (April 13, 2016).

*B. What is the Agency's Authority for Taking this Action?*

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this

determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)(i)). TSCA furthermore prohibits such manufacturing or processing from commencing until EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

### *C. Applicability of General Provisions*

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the

significant new use can commence. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

### **III. Significant New Use Determination**

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental

releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

#### **IV. Substances Subject to This Proposed Rule**

EPA is proposing significant new use and recordkeeping requirements for three chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (assigned for non-confidential chemical identities).
- Public comments and EPA's response to comments on the three direct final SNURs
- Basis for the TSCA non-section 5(e) SNURs (*i.e.*, SNURs without TSCA section 5(e) consent orders).
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VII. for more information).
- CFR citation assigned in the regulatory text section of this proposed rule.

The regulatory text section of this proposed rule specifies the activities designated as significant new uses. Certain new uses, including production volume limits (*i.e.*, limits on



manufacture volume) and other uses designated in this proposed rule, may be claimed as CBI.

The three PMN substances included in this rulemaking are not subject to consent orders under TSCA section 5(e). These cases completed Agency review prior to June 22, 2016. Under TSCA, prior to the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act on June 22, 2016, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a “significant new use.” These so-called “non-TSCA section 5(e) SNURs” are consistent with the determination made at the time and are promulgated pursuant to § 721.170. EPA has determined that every activity designated as a “significant new use” in all non-TSCA section 5(e) SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities, “(i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified” for the PMN substance.

**PMN Number P-15-276**

*Chemical name:* Functionalized carbon nanotubes (generic).

*CAS number:* Claimed confidential.

*Basis for action:* The PMN states that the substance will be used as a thin film for electronic device applications. Based on SAR analysis of test data on analogous carbon nanotubes and other respirable poorly soluble particulates, EPA identified potential lung effects and skin penetration and toxicity induction from inhalation and dermal exposure to the PMN substance. Further, EPA predicts toxicity to aquatic organisms via releases of the PMN substance to surface water. Although there is potential for dermal exposure, EPA does not expect significant occupational exposures due to the use of impervious gloves, and because the PMN is used in a liquid and is not spray applied except in a closed system. Further, EPA does not expect environmental releases during the use identified in the PMN submission. Therefore, EPA has not determined that the proposed manufacturing, processing, and or use of the substance may present an unreasonable risk to human health or the environment. EPA has determined, however, that any use of the substance without the use of impervious gloves, where there is potential for dermal exposure; manufacturing the PMN substance for use other than as a thin film for electronic device applications; manufacturing, processing, or using the PMN substance in a form other than a liquid; use of the PMN substance involving an application method that generates a mist, vapor, or aerosol except in a closed system; or any release of the PMN substance into surface waters or disposal other than by landfill or incineration may cause serious health effects or significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(3)(ii) and (b)(4)(ii).

*Recommended testing:* EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS

Test Guideline 850.1300); an algal toxicity test (OCSPP Test Guideline 850.4500); a 90-day inhalation toxicity test (OPPTS 870.3465) with additional testing parameters beyond those noted at CFR 870.3465, for using the 90-day subchronic protocol for nanomaterial assessment; a two-year inhalation bioassay (OPPTS Test Guideline 870.4200); and a surface charge by electrophoresis (for example, using ASTM E2865-12 or NCL Method PCC-2 – Measuring the Zeta Potential of Nanoparticles) would help characterize the health and environmental effects of the PMN substance.

*CFR citation:* 40 CFR 721.10902.

### **PMN Number P-15-378**

*Chemical name:* Diisocyanato hexane, homopolymer, alkanolic acid-polyalkylene glycol ether with substituted alkane (3:1) reaction products-blocked (generic).

*CAS number:* Claimed confidential.

*Basis for action:* The PMN states that the substance will be used as a dual cure/UV cure adhesion/barrier coating for wood substrates. Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory sensitization.

Furthermore, the National Institute for Occupational Safety and Health (NIOSH) alert at <http://www.cdc.gov/niosh/docs/2006-149/pdfs/2006-149.pdf> summarizes four case reports: one death and several incidents of asthma or other respiratory disease following exposure to methylenebis(phenyl isocyanate) (MDI) during spray-on truck bed lining operations. For this PMN substance, a significant new use is any use of the substance without a NIOSH-certified particulate respirator with an APF of at least 10 where there is a potential for inhalation exposure, or any use in consumer products. For new isocyanates

submitted as PMNs, EPA expects to issue TSCA section 5(e) orders imposing 0.1% limits on total residual isocyanates and greater levels of respiratory protection (at least an APF of 50, or 1000 if used in a process that generates a vapor or particulate), and no consumer use. The Agency would then likely issue a SNUR defining the significant new use as total residual isocyanates exceeding that 0.1% limit and any use in a consumer product. However, as mentioned in Unit VI., below, and in the original May 16, 2016 direct final rule, EPA designated that date as the cutoff date for determining whether the new use is ongoing. Furthermore, a Notice of Commencement of Manufacture or Import was submitted and the chemical substance is now on the TSCA Inventory and is being used with respiratory protection with an APF of less than 50. For these reasons, EPA is not changing the terms of the original direct final SNUR for this PMN substance. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

*Recommended testing:* EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

*CFR citation:* 40 CFR 721.10913.

**PMN Number P-15-559**

*Chemical name:* Modified diphenylmethane diisocyanate prepolymer with polyol (generic).

*CAS number:* Claimed confidential.

*Basis for action:* The PMN states that the generic (non-confidential) use of the substance will be as a raw material for flexible foam. Based on SAR analysis of analogous diisocyanates, EPA identified concerns for potential dermal and respiratory sensitization from dermal and inhalation exposures, and for pulmonary toxicity from inhalation exposure, to the PMN substance where the average molecular weight is below 7,500 daltons and any molecular weight species is below 1,000 daltons. For the molecular weight distribution described in the PMN, significant occupational exposures are not expected. Therefore, EPA has not determined that the proposed manufacture of the substance may present an unreasonable risk. EPA has determined, however, that any manufacture of the PMN substance with an average molecular weight below 7,500 daltons, and where any molecular weight species is below 1,000 daltons may cause serious health effects. For new isocyanates submitted as PMNs, EPA expects to issue TSCA section 5(e) orders imposing 0.1% limits on total residual isocyanates and greater levels of respiratory protection (at least an APF of 50, or 1000 if used in a process that generates a vapor or particulate), and no consumer use. The Agency would then likely issue a SNUR defining the significant new use as total residual isocyanates exceeding that 0.1% limit and any use in a consumer product. However, as mentioned in Unit VI., below, and in the original May 16, 2016 direct final rule, EPA designated that date as the cutoff date for determining whether the new use is ongoing. Furthermore, a Notice of Commencement of Manufacture or Import was submitted and the chemical substance is now on the TSCA Inventory and is being used with respiratory protection with an APF of less than 50. For these reasons, EPA is not changing the terms of the original direct final

SNUR for this PMN substance. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

*Recommended testing:* EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

*CFR citation:* 40 CFR 721.10920.

## **V. Rationale and Objectives of the Proposed Rule**

### *A. Rationale*

During review of the PMNs submitted for the chemical substances that are subject to these SNURs, EPA determined that one or more of the criteria of concern established at § 721.170 were met. For additional discussion on these chemical substances, see Units II. and IV. of this proposed rule.

### *B. Objectives*

EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this proposed rule:

- EPA would receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.

- EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.

- EPA would be able to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination, before the described significant new use of the chemical substance occurs.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at <https://www.epa.gov/tscainventory>.

## **VI. Applicability of the Proposed Rule to Uses Occurring Before the Effective Date of the Final Rule**

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this proposed rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage

in a use that has been identified as a significant new use. The identities of the three chemical substances subject to this proposed rule have been claimed as confidential and EPA has received no post-PMN *bona fide* submissions (per §§ 720.25 and 721.11). Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this proposed rule are ongoing.

Therefore, as mentioned in the original May 16, 2016 direct final rule, EPA designated that date as the cutoff date for determining whether the new use is ongoing. Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified as of that May 16, 2016 date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions, expires. If such a person met the conditions of advance compliance under § 721.45(h), the person would be considered exempt from the requirements of the SNUR. Consult the **Federal Register** document of April 24, 1990 (55 FR 17376) for a more detailed discussion of the cutoff date for ongoing uses.

## **VII. Development and Submission of Information**

EPA recognizes that TSCA section 5 does not require developing any particular new information (e.g., generating test data) before submission of a SNUN. There is an exception: development of test data is required where the chemical substance subject to the SNUR is also subject to a rule, order or consent agreement under TSCA section 4 (see TSCA section 5(b)(1)).



In the absence of a TSCA section 4 test rule covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Guidelines for Pesticides and Toxic Substances.”

The recommended tests specified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs and define the terms of any potentially necessary controls if the submitter provides detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.

## **VIII. SNUN Submissions**

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25. E-PMN software is available electronically at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn>.

## **IX. Scientific Standards, Evidence, and Available Information**

EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the risk assessment documents included in the public docket. These information sources supply information relevant to whether a particular use would be a significant new use, based on relevant factors including those listed under TSCA section 5(a)(2).

The clarity and completeness of the data, assumptions, methods, quality assurance, and analyses employed in EPA's decision are documented, as applicable and to the extent necessary for purposes of this proposed significant new use rule, in Unit II and in the documents noted above. EPA recognizes, based on the available information, that there is variability and uncertainty in whether any particular significant new use would actually present an unreasonable risk. For precisely this reason, it is appropriate to secure a future notice and review process for these uses, at such time as they are known more definitely. The extent to which the various information, procedures, measures,

methods, protocols, methodologies or models used in EPA's decision have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for a significant new use rule.

## **X. Economic Analysis**

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule, during the development of the direct final rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2015-0810.

## **XI. Statutory and Executive Order Reviews**

### *A. Executive Order 12866*

This proposed rule would establish SNURs for three chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "*Regulatory Planning and Review*" (58 FR 51735, October 4, 1993).

### *B. Paperwork Reduction Act (PRA)*

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this proposed rule have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This proposed rule would not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

*C. Regulatory Flexibility Act (RFA)*

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

2. The SNUR submitted by any small entity would not cost significantly more than \$8,300.

A copy of that certification is available in the docket for this proposed rule.

This proposed rule is within the scope of the February 18, 2012 certification.

Based on the Economic Analysis discussed in Unit IX. And EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than \$8,300.

Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

#### *D. Unfunded Mandates Reform Act (UMRA)*

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government would be impacted by this proposed rule. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

#### *E. Executive Order 13132*

This proposed rule would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999).

*F. Executive Order 13175*

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this proposed rule.

*G. Executive Order 13045*

This proposed rule is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this proposed rule does not address environmental health or safety risks disproportionately affecting children.

*H. Executive Order 13211*

This proposed rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use”

(66 FR 28355, May 22, 2001), because this proposed rule is not expected to affect energy supply, distribution, or use and because this proposed rule is not a significant regulatory action under Executive Order

12866.

*I. National Technology Transfer and Advancement Act (NTTAA)*

In addition, since this proposed rule would not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), would not apply to this proposed rule.

*J. Executive Order 12898*

This proposed rule does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

**List of Subjects in 40 CFR Part 721**

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: October 19, 2016.

Maria J. Doa,

*Director, Chemical Control Division, Office of Pollution Prevention and Toxics.*

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

**PART 721--[AMENDED]**

1. The authority citation for part 721 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

2. Add § 721.10902 to subpart E to read as follows:

**§ 721.10902 Functionalized carbon nanotubes (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as functionalized carbon nanotubes (PMN P-15-276) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance after it has been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), and (a)(3). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(1), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible.

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80. A significant new use is manufacture, process, or use of the PMN substance



other than in a liquid formulation. A significant new use is use other than as a thin film for electronic device applications or any use involving an application method that generates a vapor, mist, or aerosol unless such application method occurs in an enclosed process. An enclosed process is defined as an operation that is designed and operated so that there is no release associated with normal or routine production processes into the environment of any substance present in the operation. An operation with inadvertent or emergency pressure relief releases remains an enclosed process so long as measures are taken to prevent worker exposure to and environmental contamination from the releases.

(iii) *Disposal*. Requirements as specified in §721.85 (a)(1), (a)(2), (b)(1), (b)(2), (c)(1), and (c)(2).

(iv) *Release to water*. Requirements as specified in §721.90 (a)(1), (b)(1), and (c)(1).

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a) through (e), (i), (j), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

3. Add § 721.10913 to subpart E to read as follows:

**§ 721.10913 Diisocyanato hexane, homopolymer, alkanolic acid-polyalkylene glycol ether with substituted alkane (3:1) reaction products-blocked (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as diisocyanato hexane, homopolymer, alkanolic acid-polyalkylene glycol ether with substituted alkane (3:1) reaction products-blocked (PMN P-15-378) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(4), (a)(6)(ii), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified power air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.

(B) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.

(C) NIOSH-certified negative pressure (demand) supplied-air respirator with a full facepiece.

(ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(o).

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

4. Add § 721.10920 to subpart E to read as follows:

**§ 721.10920 Modified diphenylmethane diisocyanate prepolymer with polyol (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as modified diphenylmethane diisocyanate prepolymer with polyol (PMN P-15-559) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80. A significant new use of the substance is manufacture of the substance where

the average molecular weight is below 7,500 daltons, and where any molecular weight species is below 1,000 daltons.

(ii) [Reserved].

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[FR Doc. 2016-25933 Filed: 10/26/2016 8:45 am; Publication Date: 10/27/2016]